

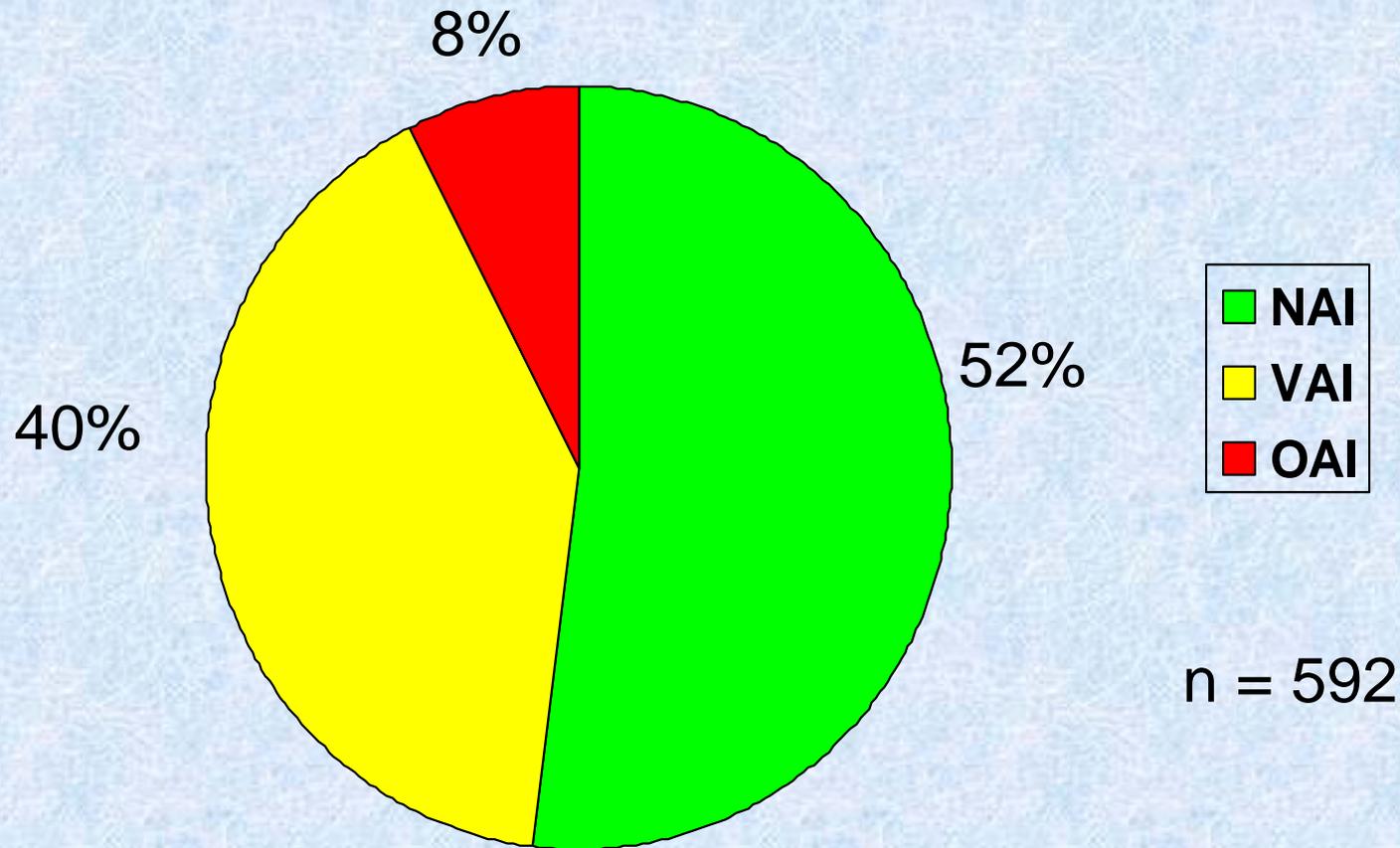
**Bioresearch
Monitoring (BIMO)
Metrics – FY'07**

BIMO Inspections Completed FY 2007

<u>Center</u>	<u>CI</u>	<u>IRB</u>	<u>Spon/Mon</u>	<u>GLP</u>	<u>Total</u>
CBER	77	28	12	13	130
CDER*	367	101	23	46	537
CDRH	183	92	40	8	323
CFSAN	0	0	0	3	3
CVM	9	na	0	9	18
All Centers	636	221	75	79	1011

* + 122 **BEQ** inspections (CDER specific) = 1133 total

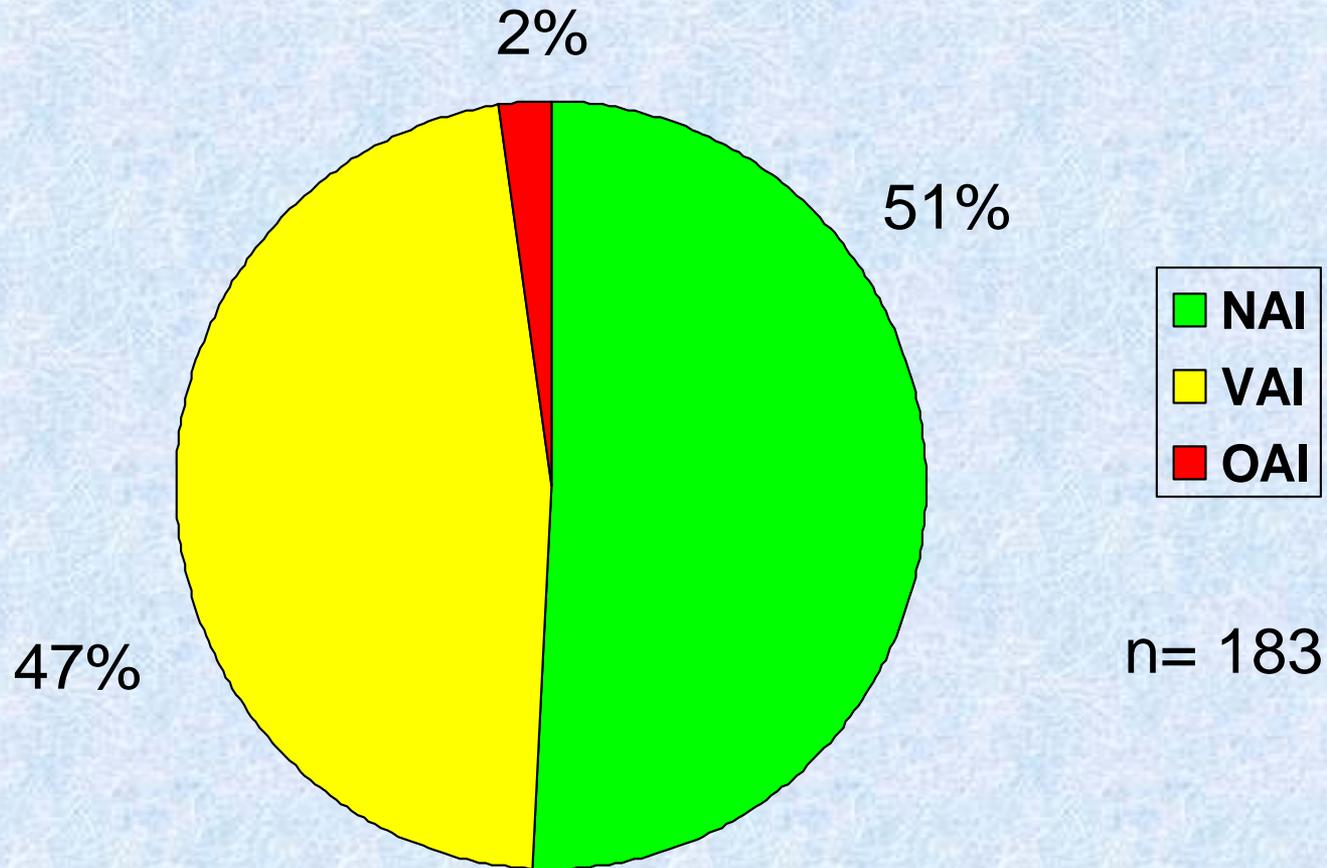
FY'07 CI Inspections Classified – All Centers



Most Common CI Deficiencies

- Failure to follow the investigational plan
- Protocol deviations
- Inadequate recordkeeping
- Inadequate accountability for the investigational product
- Inadequate subject protection – including informed consent issues

FY'07 IRB Inspections Classified – All Centers

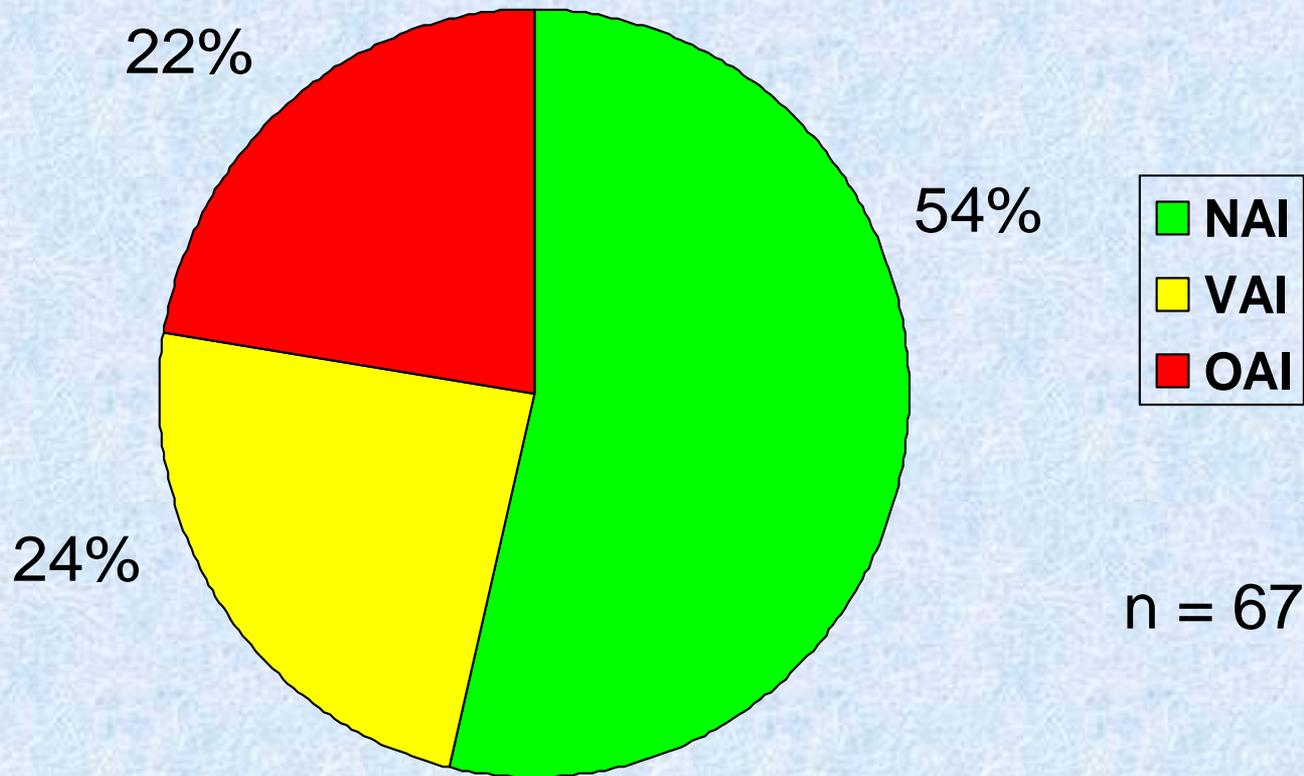


Most Common IRB Deficiencies

- Inadequate initial and/or continuing review
- Inadequate SOPs
- Inadequate membership rosters
- Inadequate meeting minutes

Specific to devices – lack of or incorrect SR/NSR determination

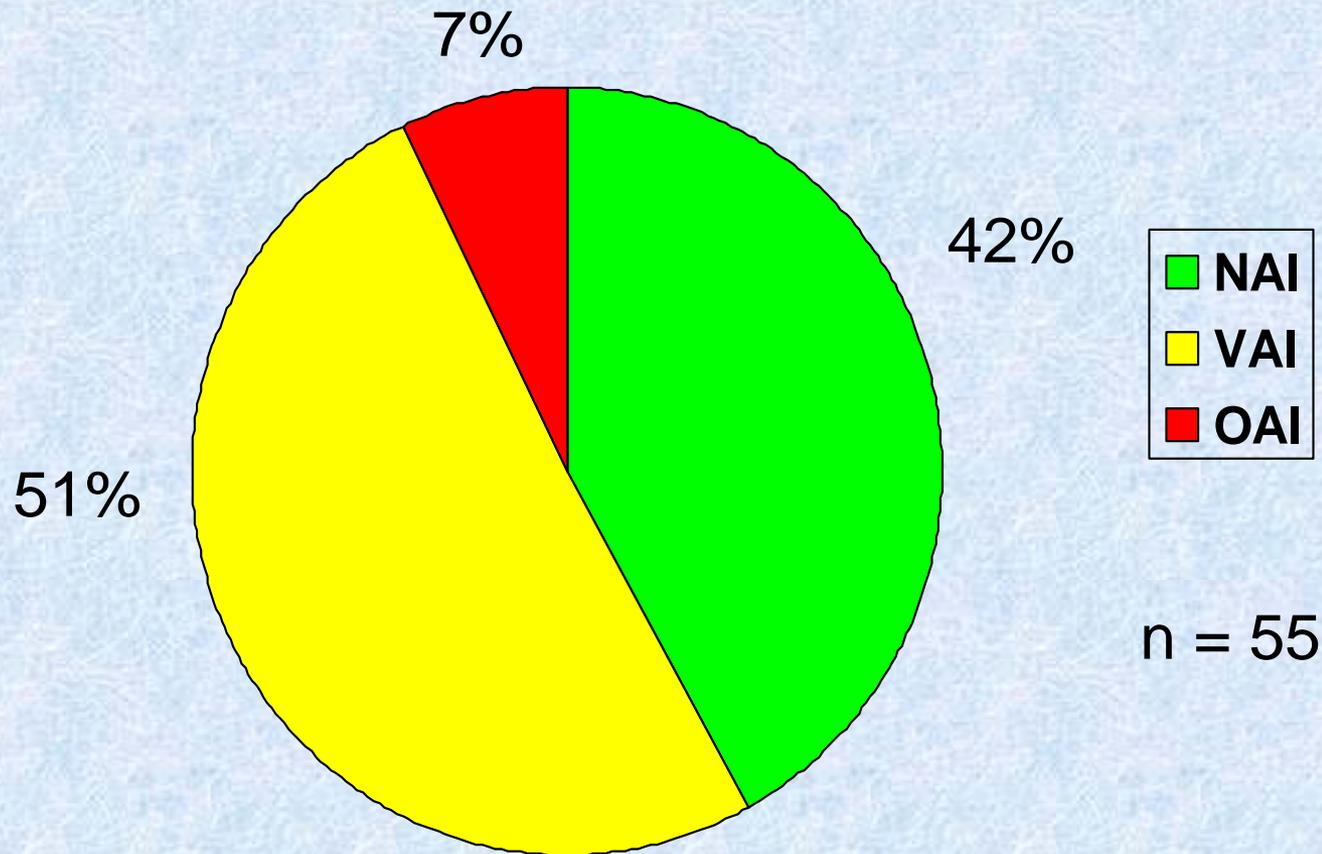
FY'07 Sponsor Inspections Classified – All Centers



Most Common Sponsor-Monitor Deficiencies

- Inadequate monitoring
- Failure to bring investigators into compliance
- Inadequate accountability for the investigational product

FY'07 GLP Inspections Classified – All Centers



International GCP CI Inspections Completed: FY 2007

<u>Center</u>	<u>Total</u>
CBER	3
CDER	104
CDRH	11*
Totals	118

* 9 CI and 2 Sponsor inspections

Common OUS deficiencies

- Similar to domestic inspectional findings
- Sponsor inspections
 - Inadequate monitoring
 - Failure to bring investigators into compliance
- CI inspections
 - Protocol deviations
 - Inadequate investigational product accountability
 - Inadequate subject protections